+

Please type a plus sign (+) inside this box → +

Under the Pap	erwork Reduction	n Act of 1995, i	no persons are required to respond to a collect	on of Information unless it contains a valid OMB	control number			
	Substitute for	r form 1449	A/PTO	Complete if Known				
1	INF	ORMAT	TION DISCLOSURE	Application Number	Divisional of 09/535,146			
		ATEME	NT BY APPLICANT  ny sheets as necessary)		ota 75			
İ				Filing Date	February 26, 2002 (A)			
1				First Named Inventor	Simon F. Williams			
				Group Art Unit	7			
L	<u> </u>			Examiner Name				
Sheet	1	of	11	Attorney Docket Number	MBX 035 DIV 1			

				U.S. PATENT DOCL	JMENTS	
Examiner Initials*	Cite No.1	US Patent D	Nocument  Kind Code 2  (if known)	Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
P.5		4,792,336		Hlavacek, et al.	12-20-1988	
A		4,826,493		Martini, et al.	05-02-1989	
		4,910,145		Holmes, et al.	03-20-1990	
		5,085,629		Goldberg, et al.	02-04-1992	
		5,124,371		Tokiwa et al.	06-23-1992	
		5,240,530		Peoples, et al.	10-05-1993	
		5,271,961		Mathiowitz, et al.	12-21-1993	
		5,306,286		Stack, et al.	04-26-1994	
		5,334,698		Witholt, et al.	08-02-1994	
1		5,443,458		Eury	08-22-1995	
		5,480,394		Ishikawa	01-02-1996	
		5,480,794		Peoples, et al.	01-02-1996	
		5,489,470		Noda	02-06-1996	
		5,502,116		Noda	03-26-1996	
		5,502,158		Sinclair et al.	03-26-1996	
		5,512,669		Peoples, et al.	04-30-1996	
		5,534,432		Peoples, et al.	07-09-1996	
		5,536,564		Noda	07-16-1996	
		5,551,954		Buscemi, et al.	09-03-1996	
		5,563,239		Hubbs, et al.	10-08-1996	
		5,625,030		Williams et al.	04-29-1997	
		5,629,077		Turnlund, et al.	05-13-1997	
		5,646,217		Hammond	07-08-1997	
		5,670,161		Healy, et al.	09-23-1997	
		5,705,187		Unger	01-06-1998	
		5,711,933		Bichon, et al.	01-27-1998	
		5,814,071		McDevitt, et al.	09-29-1998	
		5,824,751		Hori et al.	10-20-1998	
P.S.		5,834,582		Sinclair et al.	11-10-1998	

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.

ATL1 #502330 v1

include copy of this form with next communication to application.

MBX 035 DIV

<sup>&</sup>lt;sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3), <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document, <sup>6</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>9</sup> Applicant to place a check mark here if English language Translation is attached.

Inder the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

	Substitute for		APTO	Compl te if Known		
	STA	TEME	TION DISCLOSURE NT BY APPLICANT  ny sheets as necessary)	Application Number	Divisional of 09/535,146	
		•		Filing Date	February 26, 2002	
1				First Named Inventor	Simon F. Williams	
1				Group Art Unit		
1				Examiner Name		
Sheet	2	of	11	Attorney Docket Number	MBX 035 DIV	

			U.S. PATENT DOCU	MENTS	
Examiner Initials*	Cite No.1	US Patent Document Number Kind Code	of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
i		(if know			
P. 5		5,855,619	Caplan, et al.	01-05-1999	
		5,876,452	Athanasiou, et al.	03-02-1999	
		5,876,455	Harwin	03-02-1999	
		5,935,506	Schmitz, et al.	08-10-1999	
V		5,994,478	Asrar, et al.	11-30-1999	
P.S		6,245,537	Williams et al.	06-12-2001	
		<b></b>			
		<b></b>			
		<del> </del>	<del></del>		
		<del> </del>	<del></del>		
<del>  </del>		<del> </del>	<del></del>		
<b> </b>			<del></del>		
		ļ	<del></del>		<u> </u>
<b> </b>		<del> </del>			
<del></del>		<del> </del>	- <del></del>	<del></del>	
<del></del>		1	<del></del>		<del></del>
F		L		10-1-011	
Examine Signature		Peter	Srelel	Date Considered	10/9/03

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered include copy of this form with next communication to application.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>8</sup> Applicant to place a check mark here if English language Translation is attached.

-	-

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number Substitute for form 1449A/PTO Application Number Divisional f 09/535,146 **INFORMATION DISCLOSURE** STATEMENT BY APPLICANT (use as many sheets as necessary)

Filing Date February 26, 2002 First Named Inventor Simon F. Williams **Group Art Unit** Examiner Name Sneet 11 Attorney Docket Number MBX 035 DIV

					OREIGN PATENT DOCUMEN	TS		
Examiner Initials*	Cite No.1		Foreign Patent Doc		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM- DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Ts
		Office.3	Number	Kind Code <sup>b</sup> (if known)		l		
P.S.		GB	2166354	A	Imperial Chemical Industries Plc	05-08-1986		
AT		EP	0 349 505	A2	Astra Meditec AB	03-01-1990		
		EP	0 507 554	A1	Mitsui Toatsu Chemicals, Inc.	10-07-1992		
		EP	0 628 586	A1	Terumo Kabushiki Kaisha	06-10-1994		$\vdash$
		EP	0 754 467	A1	Astra Aktiebolag	01-22-1997		1
			95/03356	A1	Massachusetts Institute of Technology	02-02-1995		
			95/23250	A1	The Procter & Gamble Co.	08-31-1995		
		wo	95/33874	A1	Minnesota Mining & Manufacturing Co.	12-14-1995		
		WO	96/08535	A1	The Procter & Gamble Co.	03-21-1996		
		wo	97/07153	A1	University of Massachusetts Medical Center	02-27-1997		
		WO	98/39453	A1	Monsanto Company	09-11-1998		
		wo	98/48028	A1	Monsanto Company	10-29-1998		
Y			98/51812	A2	Metabolix, Inc.	11-19-1998		
P.S.		wo	99/32536	A1	Metabolix, Inc.	07-01-1999		
<del></del>								
								-
<del></del>						<del> </del>		-

<u></u>	<del></del>				
Examine	//		Date Considered	- <u>1</u> - /	7 ~
Signature	101	170 VO 15	Salo consideres	6010	103
Digitature	1010	<u> </u>		7 7	<i>L</i>
					·

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the Individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.

Please type a plus sign (+) inside this box →

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered, include copy of this form with next communication to application.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

PTO/SB/08A (10-96
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

	Substitute for	form 1449 <i>F</i>	/PTO	Complet if Known		
	STATE	MENT	N DISCLOSURE BY APPLICANT eets as necessary)	Application Number	Divisional of 09/535,146	
	•	•	•••	Filing Date	February 26, 2002	
				First Named Inventor	Simon F. Williams	
				Group Art Unit		
				Examiner Name		
Sheet	4	of	11	Attorney Docket Number	MBX 035 DIV	

		OTHER ART - NON PATENT LITERATURE DOCUMENTS							
Examiner's Cite No.'									
		AGOSTINI, et al., "Synthesis and Characterization of Poly-ß-Hydroxybutyrate. I. Synthesis of Crystalline DL Poly-ß- Hydroxybutyrate from DL- ß-Butyrolactone," <i>Polym. Sci., Part A-1</i> 9:2775-87 (1971).							
1		BAILEY, et al., "Synthesis of Polycaprolactone via a free radical mechanism. Free radical ring-opening polymerization of 2-methylene-1,3-dioxepane," J. Polym. Sci. Polym. Chem. 20:3021-30 (1982).							
		BEHREND, "PHB as a bioresorbable material for intravascular stents," American J. Cardiol. p. 45, TCT Abstracts (Oct. 1998).							
1		BREUER, et al., "Tissue Engineering Lamb Heart Valve Leaflets," Biotechnology & Bioengineering 50:562-67 (1996).							
		BRUHN & MÜLLER, "Preparation and characterization of spray-dried Poly(DL-Lactide) Micro Spheres," Proceed. Intern. Symp. Control. Rel. Bioact. Mater. 18:668-69 (1991).							
		BYROM, "Miscellaneous Biomaterials," in Biomaterials (D. Byrom, ed.) pp. 333-359 MacMillan Publishers: London, 1991.	-						
		CAMPBELL & BAILEY, "Mechanical properties of suture materials in vitro and after in vivo implantation in horses," Vet. Surg. 21(5):355-61 (1992).	L						
		CHU, et al., Wound Closure Biomaterials and Devices CRC Press:Boca Raton, 1996.							
		CONTI, et al., "Use of polylactic acid for the preparation of microparticulate drug delivery systems," J. Microencapsulation 9:153-166 (1992).							
V		DAMIEN & PARSONS, "Bone graft and bone graft substitutes: a review of current technology and applications," J. Appl. Biomater. 2(3):187-208 (1991).							
P-S.		DE GROOT, "Meniscal tissue regeneration in porous 50/50 copoly(L-lactide/epsilon-caprolactone) implants," Biomaterials 18(8):613-22 (1997).							

Examiner's	Poder	Saleali	Date Considered	10/9/03
Signature	100	2000	1 1	1-1/1/-

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

153.411-18 (1997).

PTO/SB/08A (10-96
Approved for use through 10/31/99. OMB 0851-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO				9A/PTO	c	Complete If Known			
				ON DISCLOSUR FBY APPLICAN		Divisional of 09/535,146	<del></del>		
		(use	as many	sheets as necessary)	Filing Date	February 26, 2002			
					First Named Inventor	Simon F. Williams			
					Group Art Unit	Omiditi: Winditi			
					Examiner Name				
Sheet		5	of	11	Attorney Docket Number	MBX 035 DIV			
Y. S.						shers:Amsterdam, The Netherlands, 1997).			
1°, 5,	_				neering of Polylactones and Polylactides		-		
1						oups," Macromolecules 26:4407-12 (1993).			
					atch used as a pericardial substitute afte c. Surg. 43(5):271-74 (1995).	er cardiac surgery: 6- and 24-month	ı		
			GABBAY, et al., "New outlook on pericardial substitution after open heart operations," Ann. Thorac. Surg. 48(6):803-12 (1989).						
					atalyzed synthesis of poly[(R)-(-)-3-hydro USA 92:6279-83 (1995).	oxybutyrate]: formation of macroscopic			
					nosubstituted-R-propiolactones Using T	rialkylaluminum-Water Catalytic Systems			

Examiners	2	C 177	Date Considered	. / / ~
Signature	0101	TO NOTA	[ [	10/9/03
1.3	<del></del>	947.961	<u></u>	· / · / ·

HEYDORN, et al., "A new look at pericardial substitutes," J. Thorac. Cardiovasc. Surg. 94:291-96 (1987).

GUGALA, et al., Regeneration of segmental diaphyseal defects in sheep tibiae using resorbable polymeric membranes: a preliminary study," J. Orthop. Trauma. 13(3):187-95 (1999).

HEIN, et al., "Biosynthesis of poly(4-hydroxybutyric acid) by recombinant strains of Escherichia coli," FEMS Microbiol. Lett.

HADLOCK, et al., "Ocular cell monolayers cultured on biodegradable substrates," Tissue Eng. 5(3):187-96 (1999).

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

	PTO/SB/0	BA (10-96
Approved for use through	10/31/99. OMB	0651-0031

Please type a plus sign (+) inside this box →	+	

(1989).

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

	Substil	tute for form 1449	A/PTO .	C	omplete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	Divisional of 09/535,146			
		lase as many s	needs as necessary)	Filing Date	February 26, 2002	
				First Named Inventor	Simon F. Williams	
				Group Art Unit		
				Examiner Name		
Sheet	1	6 of	11	Attorney Docket Number	MBX 035 DIV	
P. S	No.1	item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published  HOCKING & MARCHESSAULT, "Syndiotactic poly[(R,S)-ß-hydroxybutyrate] isolated from methyaluminoxane-catalyzed polymerization," Polym. Bull. 30:163-70 (1993).			-	
1		HOCKING & MA ed.), pp. 48-96,	RCHESSAULT, "Biopolye Chapman and Hall: Londo	sters" in <u>Chemistry and Technology c</u> n, 1994.	of Biodegradable Polymers, (G.J.L. Griffin,	
		HOLMES, "Biolo Polymers (Basso	ogically Produced (R)-3-hy ett, ed.), pp. 1-65, Elsevier:	droxyalkanoate Polymers and Copoly London, 1988.	mers," in <u>Developments in Crystalline</u>	
		HORI, et al., "Ch 36:4703-05 (199	nemical synthesis of high m 16).	olecular weight poly(3-hydroxybutyra	ite-co-4-hydroxybutyrate)," Polymer	
7		HORI, et al., "Ri Distannoxane C	ng-Opening Copolymerizat omplexes: Synthesis of Ne	ion of Optically Active ß-Butyrolacton w Biodegradable Polyesters," Macron	e with Several Lactones Catalyzed by molecules 26:4388-90 (1993).	

<u> </u>	<u> </u>	· · · · · · · · · · · · · · · · · · ·			
Examiner's Signature	Peter	Srekels	Date Considered	10/9/03	

HORI, et al., "Ring-Opening Polymerization of Optically Active B-Butyrolactone Using Distannoxane Catalysts: Synthesis of

HUTMACHER, et al., "A review of material properties of biodegradable and bioresorbable polymers and devices for GTR

KEMNITZER, et al., "Preparation of predominantly Syndiotactic Poly(ß -hydroxybutyrate) by the Tributylin Methoxide Catalyzed Ring-Opening Polymerization of racemic ß-Butyrolactone," Macromolecules 26:1221-29 (1993).

KOOSHA, "Preparation and characterization of biodegradable polymeric drug carriers," Ph.D. Dissertation, 1989, Univ.

KISHIDA, et al., "Formulation-assisted biodegradable polymer matrices," Chemical and Pharmaceutical Bulletin 37:1954-56

High Molecular Wright Poly(3-hydroxybutyrate)," Macromolecules 26:5533-34 (1993).

and GBR applications," Int. J. Oral Maxillofac. Implants 11(5):667-78 (1996).

Nottingham, UK., Diss. Abstr. Int. B 51:1206 (1990).

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered, include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number 2 See attached Kinds of U.S. Patent Documents. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). \* For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>6</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language

Please type a plus sign (+) inside this box →	+	
---	---	--

PTO/SB/08A (10-96 Approved for use through 10/31/99. OMB 0651-0031 Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

		Ŀ	
•	J	L	
	1	ľ	

Under the I	Paperwork Reduction	on Act of 1995, n	o persons are required to respond t	o a collection of information unless it contains a va-	iid OMB control number
	Substitute fo	r form 1449/	VPTO		
				Co	omplete if Known
	INFOF	RMATIO	N DISCLOSURE	Application Number	Divisional of 09/535,146
	STATI	EMENT:	BY APPLICANT		
	(use	as many sh	eets as necessary)		
				Filing Date	February 26, 2002
ł				First Named Inventor	Simon F. Williams
ļ				Group Art Unit	
				Examiner Name	
Sheet	7	of	11	Attorney Docket Number	MBX 035 DIV

E	011	OTHER ART - NON PATENT LITERATURE DOCUMENTS	
Examiner's Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T²
P.S.		KOOSHA, et al., "Polyhydroxybutyrate as a drug carrier," Crit. Rev. Ther. Drug Carrier Syst. 6(2):117-30 (1989).	
1		KUSAKA, et al., "Microbial synthesis and Physical Properties of ultra-high-molecular-weight poly[(R)-3-hydroxybutyrate]," Pure Appl. Chem. A35:319-35 (1998).	
		LAFFERTY, et al., "Microbial Production of Poly-b-hydroxybutyric acid" in <u>Biotechnology</u> (Rehm & Reed, Eds.), pp. 135-76, Verlagsgesellschaft:Weinheim, 1988.	
		LAMBA, et al., Polyurethanes in Biomedical Applications (CRC Press:Boca Raton, Florida, 1998).	
		LANZA, et al., Principles of Tissue Engineering (Academic Press:Austin, 1997).	
		LE BORGNE, et al., "Stereoelective polymerization of ß-butyrolactone," Polymer 30:2312-19 (1989).	
		MALM, et al., "A new biodegradable patch for closure of atrial septal defect. An experimental study," Scand. J. Thorac. Cardiovasc. Surg. 26(1):9-14 (1992).	-
		MALM, et al., "Enlargement of the right ventricular outflow tract and the pulmonary artery with a new blodegradable patch in transannular position," Eur. Surg. Res. 26(5):298-308 (1994).	
		MALM, et al., "Prevention of postoperative pericardial adhesions by closure of the pericardium with absorbable polymer patches. An experimental study," J. Thorac. Cardiovasc. Surg. 104(3):600-07 (1992).	
V		MATHIOWITZ & LANGER, "Polyanhydride microspheres as drug delivery systems" in Microcapsules Nanopart. Med. Pharm. (Donbrow, ed.), pp. 99-123 (CRC:Boca Raton, Florida, 1992).	_
P.S.		MAYSINGER, et al., "Microencapsulation and the Grafting of Genetically Transformed Cells as Therapeutic Strategies to rescue Degenerating Neurons of the CNS," Reviews in the Neurosciences, 6:15-33 (1995).	

Examiner's Signature	Peter	Steles	Date Considered	10/9	03	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Please type a plus sign (+) inside this box →	+	
---	---	--

PTO/SE/08A (10-96 Approved for use through 10/31/99, OMB 0651-0031 Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO		Co	mplete if Known		
	STAT	LEWEN.	ON DISCLOSURE F BY APPLICANT sheets as necessary)	Application Number	Divisional of 09/535,146
				Filing Date	February 26, 2002
				First Named Inventor	Simon F. Williams
ı				Group Art Unit	
				Examiner Name	
Sheet	8	of	11	Attorney Docket Number	MBX 035 DIV

		OTHER ART - NON PATENT LITERATURE DOCUMENTS	
Examiner's Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
P. Si		MCMILLIN, et al., "Elastomers for Biomedical Applications," Rubber Chemistry and Technology 67:417-46 (1994).	
1		MÜLLER, et al., "Poly(hydroxyalkanoates): A Fifth Class of Physiologically Important Organic Biopolymers," Angew. Chem. Int. Ed. Engl. 32:477-502 (1993).	
		NAKAMURA, et al., "Microbial synthesis and characterization of poly(3-hydroxybutyrate-co-4-hydroxybutyrate)," <i>Macromol.</i> 25:4237-41 (1992).	
		NIKLASON, et al., "Functional arteries grown in vitro," Science 284(5413):489-93 (1999).	
		NOBES, et al., "Polyhydroxyalkanoates: Materials for delivery systems," Drug Del. 5:167-77 (1998).	
		OGAWA, et al., "A New Technique to Efficiently Entrap Leuprolide Acetate into Microcapsules of Poly Lactic Acid or Copoly(Lactic/Glycolic) Acid," Chem. Pharm. Bull. 36:1095-103 (1988).	
		OTERA, et al., "Distannoxane as reverse micelle-type catalyst: novel solvent effect on reaction rate of transesterification," J. Org. Chem. 54:4013-14 (1989).	
		OTERA, et al., "Distannoxane-catalysed transesterification of 1,n-Dioldiacetates. Selective transformation of either of chemically equivalent functional groups," J. Chem. Soc. Chem. Commun. 1742-43 (1991).	
V		OTERA, et al., "Novel distannoxane-catalyzed transesterification and a new entry to , -unsaturated carboxylic acids," Tetrahedron Lett., 27:2383-86 (1986).	
P.S.		OTERA, et al., "Novel template effects of distannoxanne catalysts in highly efficient transesterification and esterification," J. Org. Chem. 56:5307-11 (1991).	

					· · · · · · · · · · · · · · · · · · ·							<u>.</u>
Examiner's	ו כע	-	C = I	. /		Date Considered	, ,		<i></i>			
	1/2/	o ^	1700	n l		pare consocied	1.		9	1/	22	
Signature	1 1/1	_/	-3 8/	יתש	1		l / D	/	7	/ -	<b>^</b> >	
							<u> </u>	_				
				•					$\overline{}$			

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to epplicant.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents, <sup>3</sup> Enter Office that issued the document, by the two-latter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>6</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Please type a plus sign (+) Inside this box →	1	

PTO/SB/08A (10-96 Approved for use through 10/31/99. OMB 0651-0031 Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

_	1.	
1	τ	

	Substitute fo	r form 1449A/	PTO	Co	omplet if Known
	STAT	EMENT E	I DISCLOSURE BY APPLICANT lets as necessary)	Application Numb r	Divisional f 09/535,146
	•		• • • • • • • • • • • • • • • • • • • •	Filing Date	February 26, 2002
				First Named Inventor	Simon F. Williams
				Group Art Unit	
				Examiner Name	
Sheet	9	of	11	Attorney Docket Number	MBX 035 DIV

		OTHER ART - NON PATENT LITERATURE DOCUMENTS	
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T²
P.S.		POUTON & AKHTAR, "Biosynthetic polyhydroxyalkanoates and their potential in drug delivery," Adv. Drug Delivery Rev. 18:133-62 (1996).	
1		RIVARD, et al., "Fibroblast seeding and culture in biodegradable porous substrates," J. Appl. Biomater. 6(1):65-68 (1995).	
		SAITO, et al., "Microbial synthesis and properties of poly(3-hydroxybutyrate-co-4-hydroxybutyrate) in Comamonas acidovorans," Int. J. Biol. Macromol. 16(2):99-104 (1994).	
		SHINOKA, et al., "Creation of viable pulmonary artery autografts through tissue engineering," <i>J. Thorac. Cardiovasc. Surg.</i> 115(3):536-46 (1998).	
		SHINOKA, et al., "Tissue engineering heart valves: valve leaflet replacement study in a lamb model" Ann. Thorac. Surg. 60(6 Suppl):S513-6 (1995).	
		SHINOKA & MAYER, "New frontiers in tissue engineering: tissue engineered heart valves" in <u>Synthetic Bioabsorbable</u> Polymer Scaffolds (Atala & Mooney, eds.) pp. 187-198 Birkhäuser Boston, 1997.	
		SIM, et al., "PHA synthase activity controls the molecular weight and polydispersity of polyhydroxybutyrate in vivo," Nat. Biotechnol. 15(1):63-67 (1997).	
		SPEER & WARREN, "Arthroscopic shoulder stabilization. A role for biodegradable materials," Clin. Orthop. (291):67-74 (1993).	
		STEINBÜCHEL & VALENTIN, "Diversity of bacterial polyhydroxyalkanoic acids," FEMS Microbiol. Lett. 128:219-28 (1995).	
P.S.		STEINBÜCHEL & WIESE, "A Pseudomonas strain accumulating polyesters of 3-hydroxybutyric acid and medium-chain-length 3-hydroxyalkanoic acids," Appl. Microbiol. Biotechnol. 37:691-97 (1992).	

Examiner's	P		Date Considered		/ ~
Signature	15401	520 e14		10/8/	03
					<u>.                                  </u>

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

PTO/SB/08A (10-96 Approved for use through 10/31/99, OMB 0651-0031

ti-d-ath- Day		7.4.44	A = 1 = 1 4 5 0 5			Palent and Trademark Office: U.S. DEPARTMENT OF CO	OMMERC
			form 1449/		a a collection of information unless it contains a va	omplet If Kn wn	
		ATE	MENT	N DISCLOSURE BY APPLICANT	Application Number	Divisional of 09/535,146	
		(use	as many si	ieeus as necessary)	Filing Date	February 26, 2002	
					First Named Inventor	Simon F. Williams	
					Group Art Unit		
					Examiner Name		
heet	1	0	of	11	Attorney Docket Number	MBX 035 DIV	
				OTHER ART	NON PATENT LITERATURE DOCUM	AENTS	
Examiner's	Cite	Г			(in CAPITAL LETTERS), title of the article		T <sup>2</sup>
Initials*	No.1			item (book, magazine, journal	, serial, symposium, catalog, etc.), date, problisher, city and/or country where publish	age(s), volume-issue number(s),	'
P.S.		STEIN 1991.		"Polyhydroxyalkanoic Aci	ds," In <u>Blomaterials</u> (D. Byrom ed.), p	op. 123-213, MacMillan Publishers: London	'
1		TALJA	∖, et al., "B	ioabsorbable and biodegra	dable stents in urology," J. Endourol	. 11(6):391-97 (1997).	
					d Stereoregularity of Poly(3-hydroxy Macromolecules 24:5732-33 (1991)	butyrate) Prepared from optically Active &	
$\top$		TANG	UAY, et al	, "Current status of biodeg	radable stents," Cardiol. Clin. 12(4):	699-713 (1994).	
1		TSUR	UTA, et al.	, Biomedical Applications of	of Polymeric Materials (CRC Press, I	Boca Raton, Florida, 1993).	<del> </del>
1				I, et al., "Polyhydroxybutyn acts (Oct. 1998).	ate (PHB) Biodegradable Stent-Expe	erience in the Rabbit," American J. Cardiol.	->-
		VALEI	NTIN, et al se," J. Biote	., "Production of poly(3-hy echnol. 58:33-38 (1997).	droxybutyrate-co-4-hydroxybutyrate)	in recombinant Escherichia coli grown on	
+				ER, et al., "The use of poly ' J. Biomed. Mater. Res. 2		fts for the reconstruction of rabbit knee	<del>                                     </del>
<del></del>	+	WALL	EN & ROH	WEDDER, "Poly-B-hydrox	valakaonate from Activated Sludge."	Environ, Sci. Technol, 8:576-79 (1974).	+

Examiner's	Palar	Sind of the	Date Considered a	<u> </u>
Signature	1576	1 26 Ke 14	10/9/	$\nu$ $\supset$

Engineering (Patrick, et al., Eds.) Ch. II.5, pp.107-20 (Elsevier Science, New York, 1998)

WIDMER & MIKOS, "Fabrication of biodegradable polymer scaffolds for tissue engineering" in Frontiers in Tissue

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

PTO/SB/08A (10-9	х
Approved for use through 10/31/99. OMB 0651-003	
Delicional Committee of the Committee of	

									Palent and Tr	Approved for use through 10/31/99, OMB 0 rademark Office: U.S. DEPARTMENT OF CO	651-003 MMERC
Under the	_					are required to resp	ond to	a collection of information unless it contain	ns a valid OMB cont	trol number	
	5	Substit	ute for for	m 1449.	APTO				Compl te is	f Known	
						SCLOSUR APPLICAN		Application Number		Divisional of 09/535,146	
			(use as	many si	heets as	necessary)		Filing Date		February 26, 2002	
1								First Named Inventor		Simon F. Williams	
1								Group Art Unit			
					,			Examiner Name			
Sheet		1	1	of	L	11		Attorney Docket Number		MBX 035 DIV	
						OTHER ART	T N	ON PATENT LITERATURE DO	CUMENTS		
Examine Initials		Cite No. <sup>1</sup>				te name of the au	ithor (i umal,	n CAPITAL LETTERS), title of the a serial, symposium, catalog, etc.), da ublisher, city and/or country where p	rticle (when appr ite, page(s), volu		T
R:	5		WILLIAN	IS & PE	OPLES	, "Making plasti		reen," Chem. Br. 33:29-32 (199			
1			WILLIAN	IS & PE	OPLES	, "Biodegradab	le pla	astics from plants," CHEMTECH	126:38-44 (19:	96).	
			XIE, et al	., "Ring	g-openii	ng Polymerization	on of	ß-Butyrolactone by Thermophi	lic Lipases," M	lacromolecules 30:6997-98 (1997).	-
V			YAMADA (1997).	, et al.,	"Devel	opment of a dur	ral su	bstitute from synthetic bioabsor	rbable polymer	rs," J. Neurosurg. 86(6):1012-17	$\top$
P.S.			ZUND, e 11(3):493			ro construction	of a t	issue engineered bioprosthetic	heart valve," E	Eur. J. Cardiothorac. Surg.	T

Examiner's Stells Date Considered 10/9/03	<u> </u>					
		Peter	Steles	Date Considered	10/9/03	

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → +

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that Issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

,,,~ ∙ • Under the Pac		e e e e e e e e e e e e e e e e e e e		o person	s are required to respon	AN 3, 1 ZOUL	(2)	s it cor	Patent and	Tradem	PTO/SB/08/ proved for use through 10/31/59, OMB 06 lark Office: U.S. DEPARTMENT OF COM imber	51-0031
			om 1449		· Co	WA TRADEN					f Known	
		STA	TEME	NT B	DISCLOSU Y APPLICA	ANT	Applicati n N	lumb	er		10/082,954	
		(C	ise as ma	ny sne	ets as necessary)		Filing Date				February 26, 2002	
							First Named Inventor				Simon F. Williams	
							Group Art Unit					
							Examiner Na				<del> </del>	
Sheet	F	1	of	Γ	2	··	Attorney Doc		lumber		MBX 035 DIV	
							<del></del>				<del></del>	
						U.S. PATE	NT DOCUME!	VTS				
Examiner Initials*	Cite No.1	US Patent Document  Number Kind Code  (if known			Name of of C				ges, Columns, Lines, Where Releva assages or Relevant Figures Appea			
		1									<del></del>	
						Cox		<b>5</b>		D		
	<b> </b> -						COPY OF PA		· //		50	
		<del> </del>					- SYA	1		THE		
		<del> </del>				·		50			462 (1)	
											<u 12<="" td=""><td></td></u>	
											7	
								<b>-</b>			<del>//()</del> n	
	<del> </del>	1						<del> </del>				
		1			· · · · · · · · · · · · · · · · · · ·			-				
						OREIGN PA	TENT DOCUM	IENT	S			
Examiner Initials*	Cite No.1	Foreign Patent Document				Name of Patentee or Applicant of Cited Docume		nt	Date of Publication of Cited Document MM-DD-YYYY		Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	7°
		Office.3		ımber*	Kind Code <sup>5</sup> (if known)							
P.S.		EPA	0 452 11	1		Takeda Che	keda Chemical Industries 10-16		0-16-1991			
		<b> </b>									<del> </del>	L
			<del> </del>			<del> </del>			<b></b>			

Date Considered

10/

9/03

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.

+

Examine Signature Peter

Szelely

+

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required logicity point to	a collection whomation unless it contains a valid OMB cont	PTO/SB/08A* (10-98 Approved for use through 10/31/99, OMB 0851-0031 rademark Office: U.S. DEPARTMENT OF COMMERCE trol number			
Substitute for form 1449A/PTO	Complete if Known				
INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (use as many sheets as necessary)	Application Number	10/082,954			
(use as many sneets as necessary)	Filing Date First Named Inventor	February 26, 2002 Simon F. Williams			
	Group Art Unit				

**Examiner Name** 

Attorney Docket Number

MBX 035 DIV

		OTHER ART - NON PATENT LITERATURE DOCUMENTS	
Examiner's Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T
PS		FRASER, et al., "Controlled release of a GnRH agonist from a polyhydroxybutyric acid implant-reversible suppression of the menstrual cycle in the macaque," Acta Endocrinol 121:841-848 (1989).	
P.S.		HOLMES, et al., "Applications of PHB—a microbially produced biodegradable thermoplastic," Phys Technol 16:32-36 (1985).	
P.S.		KORSATKO, et al., "The influence of the molecular weight of poly-D(-)-3-hydroxybutyric acid on its use as a retard matrix for sustained drug release," 8th Europ. Congress of Biopharmaceutics and Pharmokinetics 1:234-242 (1987).	
P.S.		MODELLI, et al., "Kinetics of aerobic polymer degradation in soil by means of the ASTM D 5988-96 standard method," <i>J</i> Environ Polym Degr 7:109-116 (1999).	
P.S.		RENSTAD, et al., "The influence of processing induced differences in molecular structure on the biological and non-biological degradation of poly (3-hydroxybutyrate-co-3-hydroxyvalerate), P(3-HB-co-3-HV)," Polymer Degradation and Stability 63:201-211 (1999).	
		PRO PIGNAL PAR	
		MECEN	الا الا
		TC 1700	
		77700	
			_

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Stelely

Date Considered

Peter

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Examiner's

Signature

Sheet

ૈંદ્ર

03

<sup>&</sup>lt;sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>6</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>9</sup> Applicant to place a check mark here if English language Translation is attached.